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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,359	04/20/2004	Tom Westberg	F-5495 DIV (0360-0172.01)	4891
44926 7590 08/18/2008 BAXTER HEALTHCARE CORPORATION ONE BAXTER PARKWAY DF2-2E DEERFIELD, IL 60015			EXAMINER WIEST, PHILIP R	
			ART UNIT 3761	PAPER NUMBER
			MAIL DATE 08/18/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/828,359	Applicant(s) WESTBERG ET AL.	
	Examiner Phil Wiest	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/1/08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pages et al. (US 5,954,971) in view of Kamen et al. (5,350,357), and further in view of Lundback (US 4,750,868).

3. With respect to Claims 1-3 and 6, Pages et al. (hereafter Pages) discloses a blood processing system for removing leukocytes from blood comprising a plurality of blood inlets having flow control means (115v and 120v), a leukocyte filter 140, and a pump station 132, and a plurality of blood collection containers (145, 150) that receive blood from a separation device. The filter 140 communicates with blood collection containers (145, 150) that is located downstream of the filter. Pages, however, does not disclose that the plurality of flow control means comprise a first and second pump that operate in tandem, nor does Pages disclose that the pump strokes cause a continuous flow from the source and a pulsatile flow to the filter.

4. Regarding Pages' lack of a first and second pump operating in tandem, Kamen et al. (hereafter Kamen) discloses a medical fluid pumping device comprising a plurality of pumping stations that operate by applying positive and negative pressures to a

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membrane. Regarding Claims 4 and 5, pneumatic fluid pressures are applied to the pumps and valves (Column 3, Lines 15-20). The controller operates the pumps in tandem such that the first pump is in a draw stroke while the second pump is in a pump stroke, and vice versa. By using this type of alternating, tandem pumping method, it is ensured that a constant stream of fluid is being pumped through the system, thereby improving the speed at which the device operates (Column 31, Line 58 through Column 33, Line 6). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the pumping/filtering apparatus of Pages with the alternating, tandem pumping arrangement of Kamen in order to expedite pumping operation. The pumping arrangement of Kamen provides a well-known improvement over the single pump and valve arrangement of Pages.

5. Regarding Pages' lack of a continuous input / pulsatile output configuration, Lundback discloses a pumping system and method that uses a pneumatic driving means to provide a pulsatile outflow and a continuous inflow. The system of Lundback comprises two pump stations, A and V, which are in communication between the fluid inlet and outlet (see FIG 3A). The method disclosed by Lundback includes a pumping stroke and a return stroke that operate in succession to one another in order to create a continuous inflow and a pulsatile outflow (see columns 6-7). This type of pump may be used in a variety of types of systems, including blood pumping systems in order to better control the flow rate of the fluid being pumped. It would have been obvious to one of ordinary skill in the art at the time of invention to combine the blood processing system of Pages and Kamen with the pumping method of Lundback in order to provide

a continuous inflow and pulsatile outflow in order to provide a pressure-sensitive pumping system, as taught by Lundback.

Response to Arguments

6. Applicant's arguments filed 5/1/08 have been fully considered but they are not persuasive. Applicant argues that Pages does not teach the pumping system as claimed, and that there is no motivation to combine the Pages and Kamen references. The Examiner disagrees.

7. As stated in the action mailed 2/6/08, the examiner asserts that Pages does not teach the specifics of the pumping system as claimed, but generally teaches the function of processing blood through a leukocyte filter substantially as claimed. As discussed in the action, Kamen teaches the use of a plurality of fluid pressure activated pumping stations operating in tandem to process physiological fluid through a fluid circuit. The device comprises a control function to switch between a first mode and a second mode. As discussed in the action, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the leukocyte removal system having a plurality of inlets of Pages with the alternating, fluid pressure-activated, tandem pumping arrangement of Kamen in order to provide an alternate, well-known pumping system for transferring physiological fluids through a fluid circuit.

8. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention

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where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, applicant argues that Kamen teaches essentially continuous fluid flow, and therefore teaches away from pulsatile fluid flow to the filter. This has not been found persuasive. Simply teaching continuous flow does not necessarily teach away from pulsatile flow. Kamen does not expressly teach away from the claimed function.

9. Applicant also argues the combination of the Pages and Kamen with Lundback. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Lundback teaches a pump that has a continuous inflow and pulsatile outflow, which allows for improved flow control in systems where the supply of fluid may not be constant (Column 1, Lines 18-29). Lundback also suggests that this type of pump may be used for blood pumping devices. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the blood processing device of Pages in view of

Kamen with blood pumping means having continuous inflow and pulsatile outflow, as suggested by Lundback, in order to provide enhanced control over the flow of fluid through the system.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/
Examiner, Art Unit 3761

//Leslie R. Deak//
Primary Examiner, Art Unit 3761
14 August 2008